

REMARKS

This is a full and timely response to the non-final Official Action mailed March 8, 2010 (the "Office Action" or "Action"). Reconsideration of the application in light of the above amendments and the following remarks is respectfully requested.

Claim Status:

Under the imposition of a previous Restriction Requirement, claims 19-44 and 47-49 were withdrawn from consideration and are so marked herein. Withdrawn claim 25 was previously canceled without prejudice or disclaimer. The withdrawn claims have been amended herein consistent with the pending claims. Specifically, withdrawn claims 19, 26, 29, 33, 40, and 47 have been amended. Consequently, upon the allowance of claim 1, claims 19-24, 26-44, and 47-49 will be entitled to rejoinder and allowance. MPEP § 821.04

By the forgoing amendment, pending claims 1, 3, 5, 10, 15, and 45 have also been amended. Further, original claims 6-8 and 16 were previously cancelled without prejudice or disclaimer. Thus, claims 1-5, 9-15, 17, 18, 45 and 46 are currently pending for further action.

35 U.S.C. § 112, first paragraph:

In the recent Office Action, claims 3, 10 and 15 were rejected under 35 U.S.C. § 112, first paragraph. These claims have been carefully reviewed in light of the Examiner's comments.

While Applicant does not necessarily agree that these claims fail to comply with the written description requirement, the indicated claims have been amended herein to address the issues raised by the Examiner under 35 U.S.C. § 112, first paragraph. Following this

amendment, all the remaining claims are believed to be in compliance with 35 U.S.C. § 112 and notice to that effect is respectfully requested.

35 U.S.C. § 112, second paragraph:

In the recent Office Action, claim 10 was rejected under 35 U.S.C. § 112, second paragraph. These claims have been carefully reviewed in light of the Examiner's comments.

While Applicant does not necessarily agree that any of these claims were indefinite as filed, the indicated claims have been amended herein to address the issues raised by the Examiner under 35 U.S.C. § 112, second paragraph. Following this amendment, all the remaining claims are believed to be in compliance with 35 U.S.C. § 112 and notice to that effect is respectfully requested.

Prior Art:

Rejections under 35 U.S.C. §102(a) and (e):

(1). In the recent Office Action, claims 1-4, 9, 10, 13-15, 45 and 46 were rejected under 35 U.S.C. § 102(a) and (e) as being anticipated by U.S. Patent No. 6,623,765 to Dennis et al. ("Dennis"). For at least the following reasons, this rejection should be reconsidered and withdrawn.

Claims 1 and 45:

Claim 1 recites:

A jettable solution comprising:
an oil;
an edible surfactant;
an aqueous solution;
a drying agent; and

a pharmaceutically active ingredient solubilized into said oil;
in which said oil, said pharmaceutically active ingredient, said
surfactant, and said aqueous solution form a microemulsion;
in which said jettable solution comprises a viscosity of less than
approximately 5 centipoise and a surface tension approximately between 25 to
60 dynes per centimeter.
(Emphasis added).

Similarly, claim 45 recites:

A jettable solution comprising:
a water insoluble pharmaceutically active ingredient;
a drying agent; and
a means for forming an emulsion including said pharmaceutically
active ingredient,
in which said means for forming an emulsion is configured to create
said jettable solution with a viscosity of less than approximately 5 centipoise
and a surface tension approximately between 25 to 60 dynes per centimeter.
(Emphasis added).

Support for the amendments to claims 1 and 45 can be found in Applicant's originally
filed specification at, for example, paragraphs [0031] and [0033] as well as original claim 15.

In contrast, Dennis does not teach or suggest a jettable solution comprising: . . . a
drying agent.” (Claims 1 and 45). In fact, Dennis teaches the opposite by requiring that the
microemulsion remain in a liquid form. This is evidenced where Dennis teaches
“[m]icroemulsion systems of the present invention, particularly oil and water, can be used to
dissolve substantial concentrations of oil-soluble drugs [and] can *thereafter be injected*
intravenously. (Dennis, col. 3, l. 65 through col. 4, l. 4) (emphasis added). Clearly, Dennis
requires a microemulsion that remains in liquid form and is not to be dried by a drying agent.

Furthermore, the recent Office Action concedes that “the reference does not disclose
the viscosity or the surface tension of the solution.” (Action, p. 7). The Office Action
attempts to overcome this deficiency found in Dennis by stating that “it is the position of the
Examiner that in the absence of a showing otherwise, the composition of Dennis possesses

the claimed physical properties.” (*Id.*). This is insufficient to support a rejection of Applicant’s claims.

The Office Action has admittedly failed to prove a *prima facie* case of anticipation under 35 U.S.C. §§ 102 with regard to the viscosity of the solution recited in claims 1 and 45. The burden is on the Examiner to identify where in the reference each element of the claims may be found. Therefore, because the Office Action does not identify where within the Dennis reference “[a] jettable solution . . . in which said jettable solution comprises a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 to 60 dynes per centimeter” (Claims 1 and 45) is taught, the Office Action has failed to prove a *prima facie* case of unpatentability

Respectfully, to anticipate a claim, a reference must teach each and every element of the claim, and “the identical invention must be shown *in as complete detail as contained in the ... claim.*” MPEP 2131 citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 2 USPQ2d 1051 (Fed. Cir. 1987) and *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ2d 1913 (Fed. Cir. 1989) (emphasis added). Moreover, “[t]he prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements ‘arranged as in the claim.’” *NetMoneyIn v. Verisign*, (Fed. Cir. 2008) (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542 (Fed. Cir. 1983)).

In the present case, Dennis clearly does not disclose the claimed invention with each and every claimed element in the same amount of detail or as arranged in the claim. Specifically, Dennis clearly fails to teach or suggest either the drying agent or the recited viscosity of the claimed solution. Consequently, because Dennis clearly fails to satisfy the

requirements for anticipating claims 1 and 45, the rejection of claims 1 and 45 and their dependent claims should be reconsidered and withdrawn.

(2). In the recent Office Action, claims 1, 5, 13-15, 45 and 46 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,633,226 to Owen et al. (“Owen”). For at least the following reasons, this rejection should be reconsidered and withdrawn.

Claims 1 and 45:

Claim 1 recites:

A jettable solution comprising:
an oil;
an edible surfactant;
an aqueous solution;
a drying agent; and
a pharmaceutically active ingredient solubilized into said oil;
in which said oil, said pharmaceutically active ingredient, said surfactant, and said aqueous solution form a microemulsion;
in which said jettable solution comprises a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 to 60 dynes per centimeter.
(Emphasis added).

Similarly, claim 45 recites:

A jettable solution comprising:
a water insoluble pharmaceutically active ingredient;
a drying agent; and
a means for forming an emulsion including said pharmaceutically active ingredient,
in which said means for forming an emulsion is configured to create said jettable solution with a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 to 60 dynes per centimeter.
(Emphasis added).

In contrast, Owen does not teach or suggest a jettable solution comprising: . . . a drying agent.” (Claims 1 and 45). In fact, Owen teaches the opposite by teaching that “our

microemulsions may be used to prepare *non-drying topical*, as opposed to transdermal, salves and ointments.” (Owen, col. 14, ll. 56-57) (emphasis added). Clearly, instead of including a drying agent in a jettable solution, Owen teaches a microemulsion which is not to be dried and is to be used in a *non-drying* topical.

Respectfully, to anticipate a claim, a reference must teach each and every element of the claim, and “the identical invention must be shown *in as complete detail as contained in the ... claim.*” MPEP 2131 citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 2 USPQ2d 1051 (Fed. Cir. 1987) and *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ2d 1913 (Fed. Cir. 1989) (emphasis added). Moreover, “[t]he prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements ‘arranged as in the claim.’” *NetMoneyIn v. Verisign*, (Fed. Cir. 2008) (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542 (Fed. Cir. 1983)).

In the present case, Owen clearly does not disclose the claimed invention with each and every claimed element in the same amount of detail or as arranged in the claim. To the contrary, Owen teaches away from the claimed solution comprising a drying agent. Consequently, because Owen clearly fails to satisfy the requirements for anticipating claims 1 and 45, the rejection of claims 1 and 45 and their dependent claims should be reconsidered and withdrawn.

Rejections under 35 U.S.C. §103(a):

(1). In the recent Office Action, claims 1-3, 10, 13-15, 17, 45 and 46 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 7,166,154 to Barreto (“Barreto”). For at least the following reasons, this rejection should be reconsidered and withdrawn.

The recent Office Action states “[i]t appears Applicant is attempting to invoke the 103(c) shield. This must be explicitly stated on the record.” (Action, p. 10). The Applicant would like to point out that this has already been explicitly stated on the record in the previous response. (Applicant’s response, December 10, 2009, pp. 29-30). Barreto cannot be applied against the present application as prior art because of the provisions of 35 U.S.C. § 103(c). Again, Applicant is explicitly stating that ***“the subject matter of the present application and the Barreto reference were, at the time the invention of the present application was made, owned by, or subject to an obligation of assignment to, the same person, i.e., Hewlett-Packard Development Co. LP (See MPEP § 706.02(1)(2)).”*** (Applicant’s response, December 10, 2009, pp. 29-30). Nothing else is required.

Therefore for the reasons already stated in the previous response ***“under 35 U.S.C. § 103(c), the Barreto reference cannot*** be applied as prior art against the present application under 35 U.S.C. § 103(a).” (*Id.*) (emphasis added). Therefore, the rejection of claims 1-3, 10, 13-15, 17, 45 and 46 based on Barreto should be withdrawn.

(2). In the recent Office Action, claims 11 and 12 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 7,166,154 to Barreto (“Barreto”) in view of Woo, “Formulation and physicochemical properties of macro- and micro emulsions prepared by interfacial ion-pair formation between,” 1987. As stated above, the Barreto reference cannot

be applied as prior art under 35 U.S.C. § 103 (a). Therefore, for at least the same reasons given above in connection with the rejection of claims 1-3, 10, 13-15, 17, 45 and 46, the rejection of claims 11 and 12 should be withdrawn.

(3). In the recent Office Action, claims 1, 5, 13-15, 45 and 46 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,633,226 to Owen (“Owen”). This rejection should be reconsidered and withdrawn for the same reasons given above against the application of Owen to these claims under §102. As demonstrated above, Owen actually teaches away from claims 1 and 45 as amended herein. Consequently, Owen, taken alone, cannot render obvious these claims.

Specifically, Owen does not teach or suggest a jettable solution comprising: . . . a drying agent.” (Claims 1 and 45). In fact, Owen teaches away from the present recitations of claims 1 and 45 by stating that “our microemulsions may be used to prepare ***non-drying topical***, as opposed to transdermal, salves and ointments.” (Owen, col. 14, ll. 56-57) (emphasis added). Therefore, Owen clearly teaches that the microemulsion is to be used in a non-drying topical; teaching away from the recitations of claims 1 and 45. A reference must be considered for all it teaches, including disclosures that teach away from the invention as well as disclosures that point toward the invention. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.* 776 F.2d 281, 227 U.S.P.Q. 657 (Fed. Cir. 1985).

The Supreme Court has addressed the issue of obviousness in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). The Court stated that the *Graham v. John Deere Co. of Kansas City*, 383, U.S. 1 (1966), factors still control an obviousness inquiry. Under the analysis required by *Graham* to support a rejection under § 103, the scope and content of the prior art must first be determined, followed by an assessment of the differences between the prior art

and the claim at issue in view of the ordinary skill in the art. In the present case, the scope and content of the prior art, as evidenced by Owen, did not include the claimed subject matter, particularly a jettable solution comprising a drying agent

The differences between the cited prior art and the indicated claims are significant because recitation of claims 1 and 45 provide for the efficient control of drying rates of the aqueous vesicle pharmaceutical. Thus, the claimed subject matter provides features and advantages not known or available in the cited prior art. Consequently, the cited prior art will not support a rejection of claim 1 under 35 U.S.C. § 103 and *Graham*.

(4). In the recent Office Action, claims 11 and 12 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,633,226 to Owen (“Owen”) in view of Woo, “Formulation and physicochemical properties of macro- and micro emulsions prepared by interfacial ion-pair formation between,” 1987. The rejection of claims 11 and 12 should be reconsidered and withdrawn for at least the same reasons given above in favor of the patentability of independent claim 1.

(5). In the recent Office Action, claims 11 and 12 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,623,765 to Dennis et al. (“Dennis”) in view of Woo, “Formulation and physicochemical properties of macro- and micro emulsions prepared by interfacial ion-pair formation between,” 1987. The rejection of claims 11 and 12 should be reconsidered and withdrawn for at least the same reasons given above in favor of the patentability of independent claim 1.

(6). In the recent Office Action, claims 11 and 12 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 7,166,154 to Barreto. This rejection of claims 11 and 12 should be reconsidered and withdrawn because, as demonstrated above Barreto cannot be applied against the present application as prior art because of the provisions of 35 U.S.C. § 103(c).

Conclusion:

In view of the preceding arguments, all claims are believed to be in condition for allowance over the prior art of record. Therefore, this response is believed to be a complete response to the Office Action. However, Applicant reserves the right to set forth further arguments in future papers supporting the patentability of any of the claims, including the separate patentability of the dependent claims not explicitly addressed herein. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed.

The absence of a reply to a specific rejection, issue, or comment in the Office Action does not signify agreement with or concession of that rejection, issue or comment. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment. Further, for any instances in which the Examiner took Official Notice in the Office Action, Applicants expressly do not acquiesce to the taking of Official Notice, and respectfully request that the Examiner provide an affidavit to support the Official Notice taken in the next Office Action, as required by 37 CFR 1.104(d)(2) and MPEP § 2144.03.

If the Examiner has any comments or suggestions which could place this application in better form, the Examiner is requested to telephone the undersigned attorney at the number listed below.

Respectfully submitted,

DATE: June 8, 2010

/Steven L. Nichols/
Steven L. Nichols
Registration No. 40,326

STEVEN L. NICHOLS
Director, Intellectual Property Practice Group
VANCOTT PC
36 SOUTH STATE STREET, SUITE 1900
SALT LAKE CITY, UT 84111
P 801.237.0251
M 801.414.0750
F 801.237.0853
E snichols@vancott.com